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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/914,698	01/22/2002	David Moore Glover	CCI-017US	9996

7590 12/29/2005

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EXAMINER	
FETTEROLF, BRANDON J	
ART UNIT	**PAPER NUMBER**
1642	

DATE MAILED: 12/29/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/914,698	GLOVER ET AL.	
	Examiner	Art Unit	
	Brandon J. Fetterolf, PhD	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 October 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3 and 15-21* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3 and 15-21* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

The Amendment filed on 10/06/2005 in response to the previous Non-Final Office Action (04/06/2005) is acknowledged and has been entered.

Claims 1-3 and 15-21 are currently pending and under consideration.

Information Disclosure Statement

The Information Disclosure Statement filed on 10/21/2005 has been acknowledged. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner. A signed copy of the IDS is attached hereto.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

Rejections Maintained:

Claims 1-3 and 15-21 **remain** rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for identifying a substance capable of disrupting microtubule organizing centre (MTOC) integrity by contacting an Asp polypeptide consisting of the amino acid sequence of SEQ ID NO: 1, does not reasonably provide enablement for identifying a substance capable of disrupting microtubule organizing centre (MTOC) integrity by contacting any and/or all fragments thereof having an amino acid sequence of SEQ ID NO: 1 for the reasons of record (Pages 5-7) in the Action mailed 9-24-2004 and for the reasons set forth below.

In reference to the previous action which held that the specification does not provide enablement for identifying a substance capable of disrupting microtubule organizing centre (MTOC) integrity by contacting any and/or all fragments thereof having an amino acid sequence of SEQ ID NO: 1, Applicants assert that the specification along with the state of the art provide sufficient disclosure to enable one skilled in the art to make fragments of Asp polypeptides in accordance with

the present invention. Moreover, Applicants submit that one skilled in the art would appreciate that fragments involved in the formation or maintenance of MTOC could be used to design and identify substances to disrupt said function. Furthermore, Applicants contend that the specification provides extensive description on how such substances may operate on these fragments so as to disrupt the formation or maintenance of MTOC (see, for example, the first three full paragraphs under candidate substances starting on page 20). Applicants further argue that the disclosure of the present application in addition to the state of the prior art provide sufficient disclosure for one skilled in the art to identify whether the particular fragments of the Asp polypeptide of SEQ ID NO: 1, whether the disclosed or not by the present specification, do in fact possess the requisite functional characteristic of involvement in the formation or maintenance of MTOC. Thus, Applicants assert that one skilled in the art would be able to identify the functional properties of Asp polypeptide fragments through wither standard assays known in the art through those provided in the specification. Moreover, Applicants argue that the specification provides Asp binding assays, MTOC nucleation activity assays and whole cell assays to allow for the production and identification of Asp polypeptide fragments that possess the MTOC integrity functional property which can be affected by the candidate substances of the invention. In addition, Applicants direct the Examiner's attention to MPEP 2164.02 which states that "the specification need not contain an example if the invention is otherwise disclosed in such manner that one skilled in the art will be able to practice it without an undue amount of experimentation... lack of working examples or lack of evidence that the claimed invention works described should never be the sole reason for rejecting the claimed invention on the grounds of lack of enablement." As such, Applicants contend that the present disclosure along with the state of the art renders the scope of the present claims sufficiently enabled so as to ender the disclosure of a working example unnecessary. With regard to Claim 21 specifically, Applicants assert that the specification, alone or in combination with the state of the art, provides sufficient description to enable one skilled in the art to make the claimed polypeptides. For example, Applicants direct the Examiners attention to the third full paragraph of page 9, which states, "an amino acid substitution may be made, for example from 1, 2 or 3 to 10, 20 or 30 substitutions provided that the modified sequence retains activity in maintaining microtubule organizing centre integrity, the preferably at least 50% of the activity of the Asp polypeptide shown in SEQ ID NO: 1, more preferably at least the same activity." As such, Applicants argue that it

would have been well within the ability of one skilled in the art at the time of the filing date of the present application to make a fragment of an Asp polypeptide with certain substitutions and to test the resulting fragment to confirm that it has retained the requisite functional property. Accordingly, Applicants assert that the specification sufficiently enables one skilled in the art to make, use and identify Asp polypeptide fragments possessing the required functional property of the pending claims.

These arguments have been carefully considered but are not found persuasive.

In regards to Applicants submission that the specification provides sufficient disclosure to enable one skilled in the art to make the fragments of Asp polypeptides in accordance with the present invention, the Examiner recognizes that the test of enablement is whether one reasonably skilled in the art could make or use the invention from the disclosures in the patent coupled with information known in the art without undue experimentation *see* United States v. Telectronics, Inc., 857 F.2d 778. In this instance, those of skill in the art recognize that protein chemistry is probably one of the most unpredictable areas of biotechnology see for example Burgess *et al.* (J. Cell Biol. 111:2129-2138, 1990) and Lazar *et al.* (Mol. Cell Biol. 8:1247-1252, 1998) of record. Thus, absent the evidence that a homolog or fragment thereof of an ASP polypeptide (SEQ ID NO: 1) can form and/or maintain MTOC integrity, one of skill in the art would not be able to predictably use any and all homologs, fragments or derivatives of the amino acid sequence of SEQ D NO: 1 in any method to identify a substance that disrupts MTOC integrity without undue experimentation. With regards to Applicants assertion that the specification provides adequate teaching enabling one skilled in the art to identify whether the particular fragments of the Asp polypeptide of SEQ ID NO: 1 do in fact possess the requisite functional characteristic of involvement in the formation or maintenance of MTOC via a variety of assays, the Examiner recognizes that these art-recognized procedures for screening for active polypeptides is not adequate guidance as to the nature of active derivatives that may be constructed, but is merely an invitation to the artisan to use the current invention as a starting point for further experimentation. Even if an active or binding site were identified in the specification, they may not be sufficient, as the ordinary artisan would immediately recognize that an active or binding site must assume the proper three-dimensional configuration to be active, which conformation is dependent upon surrounding residues; therefore substitution of non-essential residues can often destroy activity. The art recognizes that function cannot be predicted from

structure alone [Bork (2000) "Powers and Pitfalls in Sequence Analysis: The 70% Hurdle." Genome Research **10**:398-400; Skolnick and Fetrow (2000) "From gene to protein structure and function: novel applications of computational approaches in the genomic era." Trends in Biotech. **18**(1): 34-39, especially p. 36 at Box 2; Doerks *et al.*, (June 1998) "Protein annotation: detective work for function prediction." Trends in Genetics **14**(6): 248-250; Smith and Zhang (November 1997) "The challenges of genome sequence annotation or 'The devil is in the details'." Nature Biotechnology **15**:1222-1223; Brenner (April 1999) "Errors in genome annotation." Trends in Genetics **15**(4): 132-133; Bork and Bairoch (October 1996) "Go hunting in sequence databases but watch out for the traps." Trends in Genetics **12**(10): 425-427]. Moreover, the Examiner recognizes that the specification need not contain an example if the invention is otherwise disclosed in such manner that one skilled in the art will be able to practice it without an undue amount of experimentation... lack of working examples or lack of evidence that the claimed invention works described should never be the sole reason for rejecting the claimed invention on the grounds of lack of enablement as set forth in MPEP 2164.02. However, as noted above, those of skill in the art recognize that protein chemistry is probably one of the most unpredictable areas of biotechnology as set forth by Burgess *et al.* (J. Cell Biol. 111:2129-2138, 1990) and Lazar *et al.* (Mol. Cell Biol. 8:1247-1252, 1998) of record. With regard to Applicants arguments pertaining specifically to claim 21, the Examiner reiterates the unpredictability of amino acid substitution and that procedures for screening for active polypeptides is merely an invitation to the artisan discussed above. As such, due to the large quantity of experimentation necessary to generate the infinite number of derivatives recited in the claims and possibly screen same for activity, the lack of direction/guidance presented in the specification regarding which structural features are required in order to provide activity, the absence of working examples directed to same, the complex nature of the invention, the state of the prior art which establishes the unpredictability of the effects of mutation on protein structure and function, and the breadth of the claims which fail to recite any structural or functional limitations, undue experimentation would be required of the skilled artisan to make and/or use the claimed invention in its full scope.

Therefore, NO claim is allowed

All other rejections and/or objections are withdrawn in view of applicant's amendments and arguments there to.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brandon J. Fetterolf, PhD whose telephone number is (571)-272-2919. The examiner can normally be reached on Monday through Friday from 8:30 to 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeff Siew can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Brandon J Fetterolf, PhD
Examiner
Art Unit 1642

JEFFREY SIEW
SUPERVISORY PATENT EXAMINER
12/22/05

BF